

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:
All Actions

No. 1:19-md-2875-RBK-KMW

Hon. Robert B. Kugler
Hon. Karen M. Williams
Hon. Thomas I. Vanaskie

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL
THE PRODUCTION OF DOCUMENTS WITHHELD AS CHINESE STATE SECRETS**

TABLE OF CONTENTS

INTRODUCTION1

LEGAL ARGUMENT.....2

 I. THE DOCUMENTS DO NOT CONTAIN STATE SECRETS2

 II. PLAINTIFFS’ SIGNIFICANT INTEREST IN THE DOCUMENTS
 EXCEEDS THAT OF THE ATTENUATED STATE SECRET
 INTEREST.....15

CONCLUSION.....17

TABLE OF AUTHORITIES**CASES**

<i>Autodesk, Inc. v. ZWCAD Software Co. Ltd.</i> , No. 5:14-cv-01409-EJD, 2015 WL 1928184 (N.D. Cal. Mar. 27, 2015)	2,16,17
<i>Masimo Corp. v. Mindray DS USA, Inc.</i> , No.: SACV 12-02206, 2014 WL 12589321 (C.D. Cal. May 28, 2014)	2,16
<i>Meggitt (Orange Cty.), Inc. v. Nie Yongzhon</i> , No. SACV 13-0239-DOC, 2015 WL 1809354 (C.D. Cal. Apr. 21, 2015)	2
<i>Munoz v. China Expert Tech., Inc.</i> , No. No. 07 Civ. 10531, 2011 WL 5346323 (S.D.N.Y. Nov. 7, 2001)	2,15
<i>Richmark Corp. v. Timber Falling Consultants</i> , 959 F.2d 1468 (9th Cir.1992)	2,15,16
<i>Schindler Elevator Corp. v. Otis Elevator Co.</i> , 657 F. Supp. 2d 525 (D.N.J. 2009).	2
<i>Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa</i> , 482 U.S. 522, 544 n. 29 (2011).....	15
<i>United States v. Vetco, Inc.</i> , 691 F.2d 1281 (9th Cir.), <i>cert. denied</i> , 454 U.S. 1098 (1981).....	16

STATUTES

Article 2 of the Law of the People’s Republic of China on Guarding State Secrets	<i>passim</i>
Article 9 of the Law of the People’s Republic of China on Guarding State Secrets	<i>passim</i>
Article 48 of the Law of the People’s Republic of China on Guarding State Secrets	3,4,6

REGULATIONS

Article 27 of the Implementing Regulations of the Law of the People’s Republic of China on Guarding State Secrets.....	3,5,6
Article 16 of the Regulations of the Peoples Republic of China on Disclosure of Government Information	3

OTHER AUTHORITY

Restatement (Third) of Foreign Relations Law § 442	15
--	----

INTRODUCTION

ZHP continues to withhold at least thirty-six non-duplicative documents as Chinese state secrets that Plaintiffs seek to compel on this application. As stated below, there is an open question as to whether certain documents listed by ZHP are duplicates, and Plaintiffs have inquired of ZHP to confirm. This issue should be resolved easily as part of this motion.

Chinese state secrets are limited to “matters that have *a vital bearing on State security and national interests*,” Article 2 of the Law of the People’s Republic of China on Guarding State Secrets, and “matters ... *likely to prejudice State security and national interests*,” Article 9.4 of the same law. ZHP has not met *its burden* of showing these documents constitute state secrets under these provisions, resting on vague assertions rather than any particularized showing of specific harm to the vital national interests of China. To the extremely limited degree any of these documents could remotely fit within any of the definitions, Plaintiffs’ interest in receiving the discovery necessary to support their claims based on ZHP’s willfully reckless manufacture of valsartan with carcinogenic nitrosamine contamination – and fraudulent failure to disclose the contamination until a customer discovered the issue and forced ZHP’s hand – is far more significant.

In the alternative, the Court can order ZHP to produce the documents, redacting only the statements by the Chinese government entity at issue, and leaving all factual and public information unredacted – including information concerning non-Chinese regulatory authorities, as ZHP’s Chinese counsel has agreed to be a reasonable solution.

LEGAL ARGUMENT

I.

THE DOCUMENTS DO NOT CONTAIN CHINESE STATE SECRETS

The “party relying on foreign law has the burden of showing that such law bars production.” *Schindler Elevator Corp. v. Otis Elevator Co.*, 657 F. Supp. 2d 525, 532 (D.N.J. 2009). Given this burden, **Chinese state secret laws “are viewed with some skepticism in U.S. courts.”** *Munoz v. China Expert Tech., Inc.*, No. No. 07 Civ. 10531, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2001) (Ex. A to the Certification of Adam M. Slater in Support of Plaintiffs’ Motion to Compel)¹; *see also Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1477 (9th Cir.1992) (rejecting the withholding party’s invocation of Chinese state secret law); *Meggitt (Orange Cty.), Inc. v. Nie Yongzhon*, No. SACV 13–0239–DOC, 2015 WL 1809354, *11 (C.D. Cal. Apr. 21, 2015) (same) (Ex. B); *Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, No. 5:14–cv–01409–EJD, 2015 WL 1928184, at *4 (N.D. Cal. Mar. 27, 2015) (same) (Ex. C); *Masimo Corp. v. Mindray DS USA, Inc.*, No.: SACV 12-02206, 2014 WL 12589321, at *3 (C.D. Cal. May 28, 2014) (same) (Ex. D).

During the Parties’ March 26, 2021 meet and confer, ordered by the Court with a court reporter in attendance, ZHP specifically identified the Chinese law provisions relied on to justify non-production. This includes Article 2 and Article 9.4 of the Law of the People’s Republic of China on Guarding State Secrets, and in a few instances Article 27 of the Implementing

¹ Unless otherwise noted, all exhibits are from this certification.

Regulations of the Law of the People's Republic of China on Guarding State Secrets.² 3/26/21 Tr. 13:23-25, 31:10-22, 32:7-16, 36:3-9 (Ex. E).

Article 2 states: “**State secrets shall be matters that have a vital bearing on State security and national interests and, as determined according to statutory procedures, are known by people within a certain scope for a given period of time.**” 3/26/21 Tr. 24:1-4. (Ex. F).

Article 9.4 states: “**The following matters involving State security and national interests shall be determined as State secrets if the divulgence of such matters is likely to prejudice State security and national interests in the fields such as political affairs, economy,**

² Chinese counsel confirmed that other provisions listed by ZHP in its spreadsheet do not identify substantive obligations, but rather the consequences for a violation. The first – Article 48 – describes the consequences of violating Chinese state secrecy laws. (Ex. F). It does not concern the definition of a state secret. The second – Article 27 of the Implementing Regulations of the Law of the People's Republic of China on Guarding State Secrets – also fails to address the definition or scope of a Chinese state secret. (Ex. G). 3/26/21 Tr. 27:10-22. At the beginning of the meet and confer, Plaintiffs also asked about the meaning of Article 16 of the Regulations of the Peoples Republic of China on Disclosure of Government Information, which states:

Information on the internal affairs of administrative organs, including the information on personnel management, logistics management, internal work process and other aspects, may not be disclosed.

The records of discussions, process drafts, consultation letters, instruction request reports and other process-related information formed by administrative organs during performance of administrative duties and functions as well as the information on administrative law enforcement case files may not be disclosed. However if disclosure of such information is required under the provisions of laws, regulations or rules, the provisions shall prevail.

(Ex. H). When Plaintiffs asked if Article 16 “protects internal administrative information,” ZHP replied, “[Y]ou’re right – it’s about the internal administration, the administration of information.” 3/26/2021 Tr. 13:13-22, 14:2-4. ZHP did not rely on Article 16 during the remainder of the meet and confer, and it could not, as none of the documents concerned the internal administration of the Chinese government. Additionally, although ZHP cites other provisions in its log, those provisions were not invoked during the meet and confer as justifying the withholding of any specific document, and they do not bear on the scope of a Chinese state secret, as ZHP’s counsel agreed during the meet and confer.

national defense and foreign affairs: ... (4) secrets in the national economic and social development Secrets of political parties that conform to the provisions of the preceding paragraph shall be State secrets.” (Ex. F).

ZHP’s counsel also relied on Article 48, stating:

Article 48 of the PRC on guarding state secrets is about – the articles of the regulation of the PRC on disclosure of government information is also relevant because, you know, as I said in my declaration, almost every state secret document -- every document contains state secrets and those documents are kept or prepared or drafted or circulated by the governments, so it's essentially this regulation applies to every document, government document. Then the government has the right to classify which and whether the document is a state secret document.

3/26/21 Tr. 21:2-15. However, Article 48 is simply a provision setting forth the consequences of a violation of a state secret law, as it states:

In the case of any of the following acts in violation of the provisions of this Law, disciplinary measures shall be imposed in accordance with the law; if the act constitutes a criminal offense, criminal liability shall be imposed in accordance with the law:

- (1) Illegally obtaining or possessing State secret carriers;
- (2) Buying, selling, transmitting or privately destroying State secret carriers;
- (3) Transmitting State secret carriers through channels without any security measures such as ordinary mail and express delivery;
- (4) Mailing or consigning State secret carriers out of China or carrying or transmitting State secret carriers out of China without approval by the relevant authority;
- (5) Illegally reproducing, recording or storing State secrets;
- (6) Involving State secrets in private contacts or correspondence;
- (7) Transmitting State secrets on the Internet or any other public information network or via wire or wireless communications without any security measures;

- (8) Connecting a secret-related computer or secret-related storage equipment to the Internet or any other public information network;
- (9) Without taking any protective measures, exchanging information between a secret-related information system and the Internet or any other public information systems;
- (10) Using a non-secret-related computer or non-secret-related storage equipment to handle information pertaining to State secrets;
- (11) Uninstalling or revising the security technology programs or management programs of a secret-related information system without approval; and
- (12) Presenting as a gift, selling, discarding, or altering the purpose of, a secret-related computer or secret-related storage equipment that is no longer in use and has not been approached with security technology.

Where a person commits any of the acts set forth in the preceding paragraph but such act does not constitute a criminal offense and disciplinary measures are not applicable, the relevant secret-guarding administrative department shall urge his or her organ or organization to deal with the person.

(Ex. F). This law clearly does not apply to every government document. Rather, it simply describes the consequences of disclosing state secrets as defined in Articles 2 and 9.

ZHP also relies on Article 27. 3/26/21 Tr. 31:10-22. That article states:

The entity that holds a meeting or organizes any other activity that involves State secrets shall take the following confidentiality measures:

- (1) It shall determine the classification level of the meeting or activity according to its contents, work out the confidentiality plan and limit the scope of participants;
- (2) It shall use the premises, equipment and facilities that are in compliance with the confidentiality provisions and standards of the State;
- (3) It shall manage carriers of State secrets in accordance with the confidentiality provisions of the State; and
- (4) It shall impose specific confidentiality requirements on the participants.

(Ex. G). Similar to Article 48, this regulation does not define a state secret or determine its scope in a manner that would encompass the documents at issue, and certainly not in a material way. It is not relevant to this motion.

As explained specifically below, ZHP has withheld documents that do not meet the definition of Chinese state secrets under Articles 2 and 9.4, and to the extent the criteria may be met to any marginal extent, including for the administrative provisions that are not concerned with any particular vital national interest), those state interests are far outweighed by Plaintiffs' interest in obtaining this information. The documents are addressed below by the number assigned on the log produced by ZHP, which was used to identify each document during the meet and confer.

3. PRINBURY00142827:³ ZHP log describes this document as “[m]eeting minutes of a meeting dated 12 June 2017 between ZHP and Chinese Center for Drug Evaluation [sic] regarding **improving the quality of the product** and register to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration.” During the meet and confer, ZHP disclosed that this document discussed the bioequivalence determinations of valsartan. 22:2-23:7. This description represents that the document addresses a basic issue regarding the efficacy of the drug. It does not satisfy ZHP’s burden to establish it has “a vital bearing on State security and national interests” under Article 2 or “is likely to prejudice State security and national interests” under

³ Plaintiffs have numbered these documents to match the number on ZHP’s Chinese state secret log that were withheld in their entirety. Plaintiffs have not challenged the documents on ZHP’s redaction log, which were only produced after the March 26, 2021 meet and confer. ZHP has represented that its withholding log contains numerous duplicative documents. For the Court’s convenience, Plaintiffs do not discuss those duplicative documents in this brief, but the Court should order the production of all duplicates when it orders the production of the documents discussed in this brief. Plaintiffs will email the withholding log in Excel format to the Court for its review.

Article 9. Therefore, ZHP must produce this document.⁴ In addition, and Plaintiffs have written to ZHP's counsel on this issue – the spreadsheet provides a long list of documents that are purported duplicates of this document, yet those documents do not all have the same date and many fall within the time period just before and including the date of the July 27, 2017 Jinsheng Lin email disclosing ZHP's knowledge that there was NDMA in valsartan. Plaintiffs reserve their rights as to this issue since if the documents are not actually duplicates, they need to be addressed separately and produced. To be clear, if the Court directs production of this document that would require production of the list found in the duplicate column (list the numbers), since ZHP represented they are all duplicates, which would obviate the need for further information on those documents. The same should hold true for all asserted duplicates of those listed herein.

8. PRINBURY00148044: According to ZHP's log, this document is "ZHP meeting minutes, discussing the plan to communicate with CDE regarding to the reply of valsartan tablet deficiency letter." Although a government official told ZHP to keep this document "confidential," the government official did not cite or otherwise reference a Chinese state secret law in support of that request. 3/26/2021 Tr. 36:10-14. ZHP further represented that the document concerns an internal meeting and does not identify the deficiency at issue. *Id.* at 38:11-18, 41:3-7. This document does not contain any information that would impact China's state security or national interests. It is not a state secret. ZHP should produce it.

9. ZHP02459190: ZHP's log states that this document is "[t]he meeting minutes between ZHP and Taizhou Medical Products Administration concerning irbesartan **genotoxic impurities.**"

⁴ The Court should note that Plaintiffs' analysis is constrained to ZHP's extremely limited descriptions of this and every other document on its log. First, as it is ZHP's burden to establish the propriety of its withholdings based on Chinese state secrets, these vague descriptions favor granting Plaintiffs' motion. Second, to the extent the Court requires more information in order to grant Plaintiffs' motion, the Court should order the production of the documents for its in camera review.

At the meet and confer, ZHP admitted that this document discusses the genotoxic impurities in irbesartan. 3/26/2021 Tr. 45:14-19. ZHP has not provided a basis for concluding this information is vital to China's state security and national interests. Moreover, the contamination in Irbesartan occurred for the same reasons as for valsartan, and in fact the July 27, 2017 email documenting the knowledge that ZHP contained NDMA also addressed a nitrosamine impurity in Irbesartan. This Court should therefore reject invocation of Chinese state secret laws to shield the document from production.

10. ZHP02557672: The log describes this document as “an invitation for a seminar on quality control of genotoxic impurities of chemical drugs, in which the Center for Drug Evaluation (CDE) of the China National Medical Products Administration expressly required the Company to keep confidential,” and it comes from the custodial file of Min Li, a 30(b)(6) witness designated by ZHP. During the meet and confer, ZHP admitted that the document does not identify itself as a “state secret.” 3/26/2021 Tr. 48:4-49:12. Instead, the government asked for it to remain confidential because it “could involve important public health concern and issue, so they want to have this seminar to discuss how to control the products, the genotoxic problem in the drugs.” *Id.* However, the contamination of ZHP's valsartan is known throughout the world, and ZHP has produced extensive documents discussing how to control or prevent the contamination. This information is not a Chinese state secret. ZHP should produce this document.

12. ZHP02604526: The log describes this document as “[a] meeting minute with National Medical Products Administration and Zhejiang Medical Products Administration, concerning feedbacks of an inspection on ZHP site.” ZHP subsequently explained that this inspection concerned the quality of its sartan drugs. 3/26/2021 Tr. 51:19-24, 52:12-18. This limited information does not establish this document is a state secret under Article 2 or 9.4, especially

when so many other regulatory agencies have inspected the same facilities. The Court should order its production.

13. ZHP02605097: According to ZHP's log, this document is "[a] meeting minute with National Medical Products Administration, concerning Irbesartan API process and **nitrosamine impurities**." ZHP subsequently added that this meeting compared the irbesartan manufacturing processes for the Chinese market with those for other markets as well as their ability to assess its **impurities**. 3/26/2021 Tr. 53:13-54:1. This description does not satisfy the definition of "state secret" in either Article 2 or Article 9.4. ZHP should produce this document.

21. ZHP02605629: The log states that this is "**a report on the detection of NDMA impurities in the valsartan API**, prepared to send to National Medical Products Administration." At the meet and confer, ZHP confirmed that the report contained mostly factual information "telling the government what happened and what measures the company has already taken," including what it has reported to the FDA. 3/26/2021 Tr. 61:23-62:8, 63:12-14. ZHP also asked "the government to provide some guidance on registration and approval of new process in China." *Id.* at 62:17-20. ZHP did not explain how this meets the definition of a Chinese state secret, as it does not. The Court should therefore order its production.

29. ZHP02608269: According to the log, this document is an "[e]mail with the Direct General [sic] of China's Food and Drug Administration of Zhejiang Province regarding the announcement [sic] of **NDMA in valsartan**." At the meet and confer, ZHP said that this email shows that China's FDA considered some of ZHP's answers on this issue unclear. 3/26/2021 Tr. 67:2-5. However, ZHP has also failed to show how divulging more specifics regarding this email would affect China's state security or national interests. The Court should order its production.

30. ZHP02608270: The log describes this document as an "[e]mail with the Direct General of China's Food And Drug Administration of Zhejiang Province regarding the announcement [sic]

of NDMA in valsartan.” During the meet and confer, ZHP explained that Document 29 is attached to this email as well as another document titled “**Explanation of valsartan impurities.**” 3/26/2021 Tr. 68:3-69:3. ZHP has announced the contamination of its valsartan throughout the world. It is not a state secret. The Court should order the production of this document.

33. ZHP02608279: ZHP’s log states that this document is “ZHP’s response to questions raised by Zhejiang Medical Products Administration.” The title of the document is “Timeline of Valsartan Event.” 3/26/2021 Tr. 81:7-9. It concerns “the cause of” the nitrosamine contamination of ZHP’s valsartan and “the reason for the change of manufacturing process” that led to the contamination. *Id.* at 82:7-16. The document also discusses the FDA’s investigation into the contamination and ZHP’s response. *Id.* at 82:20-23, 83:17-20. ZHP agreed that this information should be the same as was provided to the FDA and other regulators. *Id.* at 87:5-11. It then conceded that only “Q&A section” constituted a state secret. *Id.* However, it did not explain how the Q&A section contained anything not widely discussed with other regulators or how producing this document would adversely affect China’s state security or national interests. Given the purported widespread dissemination of all this information outside of China, this document is not a state secret. The Court should grant Plaintiffs’ motion to compel its production.

39. ZHP02613610: The log describes this document as “[c]ommunications regarding the meeting between ZHP and the officials from Center of Drug Evaluation on the specification and exemption of products dated June 12, 2017.” ZHP has confirmed that this email concerns whether its valsartan was exempt from bioequivalence determinations. 3/26/2021 Tr. 96:11-16. Regardless of whether the valsartan was or was not exempt from such a determination, ZHP has not explained how this can possibly “have a vital bearing on State security and national interests” or otherwise prejudice those interests. Thus, the document is not a Chinese state secret and should be produced.

56. ZHP02615167: According to the log, this document is a “[s]ummary of the reports provided to the authorities.” ZHP conceded that this “is for internal use.” 3/26/2021 Tr. 103:2-5. It also admitted that these reports concerned the nitrosamine contamination of its valsartan and that it reported the same information to the Chinese government and the FDA as well as other foreign regulatory authorities. *Id.* at 103:18-104:20. If this documents only contains information already produced to every other foreign regulatory authority, it cannot be a Chinese state secret. The Court should order its production.

61. ZHP02621763: ZHP’s log describes this document as “[a] report intended for Zhejiang Medical Products Administration requesting guidance on data protection law.” More specifically, ZHP “was seeking the Chinese government's view about the compliance with state secrets, given there's a US litigation ongoing.” 3/26/2021 Tr. 107:15-18. “It is a question from ZHP” and does not contain the Chinese government’s response. *Id.* at 109:12. This question does not meet the definition of a Chinese state secret under Article 2 or 9.4. The Court should grant Plaintiffs’ motion to compel its production.⁵

64. ZHP02622051: The log states that document is “[a] report from Zhejiang Medical Products Administration to ZHP regarding on-site inspection.” The inspection was of ZHP’s valsartan manufacturing site and concerned “[m]anufacturing process, inventory, Chinese recall.” 3/26/2021 Tr. 115:14-15, 17-20. Further, it actually contains “recommendation [sic] from the government” based on the on-site inspection. *Id.* at 116:1-2. ZHP’s facilities have been widely criticized by the regulatory agencies that visit them. Revealing the Chinese government’s similar

⁵ ZHP has advised Plaintiffs and the Court that their Chinese counsel has approached the Chinese government to request waiver of the state secret laws so the documents can be produced, but ZHP’s counsel has provided no documentation or update. In any event, the fact that ZHP is apparently seeking leave to provide these documents indicates that ZHP does not believe they merit further withholding.

criticisms will not “have a vital bearing on State security and national interests” or otherwise prejudice those interests. The Court should order the production of this document.

65. ZHP02622054: According to the log, this document is an “[i]nspection summary of experts from National Institute for Food and Drug Control, Center for Drug Evaluation, Zhejiang Food and Drug Administration etc. between Jan. 10-Jan. 11, 2019.” At the meet and confer, ZHP revealed that the inspection focused on irbesartan and addressed its “purity.” 3/26/2021 Tr. 117:22-23, 118:17-19. Moreover, ZHP never submitted this document to the Chinese government and does not “reflect any conclusions the Chinese government reached.” *Id.* at 119:8-11, 121:13-15. Thus, ZHP has not met its burden of establishing this document is a Chinese state secret. It should be produced.

67. ZHP02622056: The log describes this document as “[a] report to Taizhou municipal government regarding public sentiment.” On March 26, 2021, ZHP further explained that “[t]his document was about the -- some untrue and misleading information published online by some websites, so this may be a matter of -- that may cause public concern about public health.” Tr. 122:20-123:1. More specifically, the “misleading information” was “how ZHP seriously violation [sic] of CGMP and the information about ZHP should be subject to the Chinese government sanctions and sort of things.” *Id.* at 123:5-9. “So ZHP is telling the Chinese government about things they found online about the ZHP contamination issue with the valsartan.” *Id.* at 123:17-21. Thus, the information in this document is or was publicly available on the internet. It is public and cannot constitute a Chinese state secret under Article 2 or 9.4. The Court should order its production.

68. ZHP02622057: ZHP’s log describes this document as “[a] report to Taizhou municipal government regarding valsartan event.” More specifically, this document is “an update on the status” of the FDA’s inspection of ZHP’s facilities due to the contamination of its valsartan with

nitrosamines. 3/26/2021 Tr. 126:25-27:11. Part of the document is “factual information,” and another part contains the Taizhou government’s “viewpoints.” *Id.* 127:12-25. ZHP refused to discuss the Taizhou’s “viewpoints” further, but admitted that could be redacted in order to produce the factual information. ZHP’s counsel specifically agreed that: “[t]he factual information could be provided and the local government viewpoints could be redacted.” *Id.* at 128:11-15. Without establishing how these viewpoints “have a vital bearing on State security and national interests” or otherwise prejudice those interests, ZHP cannot continue to withhold this document as a state secret. The Court should grant Plaintiffs’ motion to that effect.

69. ZHP02622059: According to the log, this document is “[a] report to Taizhou Administration for Market Regulation regarding valsartan event.” During the meet and confer, ZHP explained that “[t]his report is update [sic] on FDA warning letters” and “the misleading information published online.” 3/26/2021 Tr. 131:20-21, 132:1-2. Both the FDA’s warning letter and the “information published online” are public. The document is not a Chinese state secret under Article 2 or 9.4. It should be produced.

70. ZHP02622064: ZHP’s log describes this document as “[a] report to Taizhou municipal government regarding valsartan event.” ZHP subsequently clarified that “[a]gain, this is about untrue information published online” “about the valsartan.” 3/26/2021 Tr. 134:6-7, 22. The “untrue information” is “that valsartan can cause cancer in human beings.” *Id.* at 135:9-11. This information is public. It is not a state secret. The Court should order its production.

79. ZHP02636529: The log states that this document is “[a] document dated Oct 22, 2018 of ZHP regarding valsartan event, intended for Taizhou municipal government.” ZHP later explained that “this document just recorded the EDQM reports, how many deficiencies they find by the EDQM report” (an investigation report by a European regulatory agency). 3/26/2021 Tr. 141:25-2. It contains “nothing specific.” *Id.* at 142:9. ZHP has already produced the EDQM

report. There is nothing in this document that meets the definition of a Chinese state secret under Article 2 or 9.4. It should be produced.

81. ZHP02636534: According to the log, this document is “A report to Zhejiang Medical Products Administration regarding progress of rectification and plan for next stage.” At the meet and confer, ZHP added that the report “talk[s] about, you know, what kind of measures the company is going to take, the next steps” in addressing the FDA’s and EU’s investigations into the contamination of its valsartan. 3/26/2021 Tr. 145:10-25. It also discusses “information published online.” *Id.* at 147:20-25. Thus, this document discusses internal matters within ZHP and how it will address concerns of foreign regulatory agencies. This does not meet the definition of a “state secret” under Article 2 or 9.4. Neither does a discussion of “information published online.” ZHP should produce this document.

82. ZHP02636534: ZHP’s log describes this document as “[a] report to Taizhou Commerce Bureau regarding the import ban of ZHP product by EU and USA.” ZHP later added that the document explains “why this import ban occurred, what measures the company has taken.” 3/26/2021 Tr. 151:10-12. This document describes ZHP’s internal actions to address foreign regulatory agencies’ actions due to the nitrosamine contamination. It is not a Chinese state secret. The Court should order its production.

88. ZHP02649530: The log states this document is “[a] report sent to National Food and Drug Administration regarding NDMA in valsartan.” During the meet and confer, ZHP explained that the document “provided factual information about how [the nitrosamine contamination] was potentially caused.” 3/26/2021 Tr. 161:1617-11. The document also discusses “the FDA’s limit for NDMA in valsartan.” *Id.* at 162:9-11. All of this information is public and not subject to Chinese state secrecy laws as defined in Articles 2 and 9.4. The Court should order its production.

In the alternative, if the Court does not order wholesale production of one or more of the listed documents in their entirety, the Court should order ZHP to produce those documents in redacted form – only redacting the statements and impressions of the Chinese government, with the “factual information” as well public information, including information related to non-Chinese regulatory agencies, unredacted. ZHP’s Chinese counsel agreed during the meet and confer that this was a reasonable approach, saying it was **“one way to do it”** and expressing no concerns that this would violate the state secret laws. 3/26/2021 Tr. 128:1-15. ZHP’s counsel of record cannot now oppose that solution and seek to undercut that statement – as counsel of record has made clear that it is relying entirely on Chinese counsel for this issue.

II.

PLAINTIFFS’ SIGNIFICANT INTEREST IN THE DOCUMENTS EXCEEDS THAT OF THE ATTENUATED STATE SECRET INTEREST

“The Supreme Court has stated that ‘[i]t is well settled that [foreign “blocking”] statutes do not deprive an American court of the power to order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute.’” *Munoz*, 2011 WL 5346323, at *1 (quoting *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa*, 482 U.S. 522, 544 n. 29 (2011)). In *Societe Nationale*, the U.S. Supreme Court endorsed the following factors “in deciding whether or not foreign statutes excuse noncompliance with discovery orders:”

- (1) “[T]he importance to the investigation or litigation of the documents or other information requested,”
- (2) “[T]he degree of specificity of the request,”
- (3) “[W]hether the information originated in the United States,”
- (4) “[T]he availability of alternative means of securing the information,” and

(5) [T]he extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located.”

Richmark, 959 F.2d at 1475 (quoting Restatement (Third) of Foreign Relations Law § 442(1)(c)) (citing *Societe Nationale*, 482 U.S. at 2556 n.28). However, these factors are “not exhaustive.” *Id.* Courts have also considered “the extent and the nature of the hardship that inconsistent enforcement would impose upon the person, ... [and] the extent to which enforcement by action of either state can reasonably be expected to achieve compliance with the rule prescribed by that state.” *Id.* (quoting *United States v. Vetco, Inc.*, 691 F.2d 1281, 1288 (9th Cir.), *cert. denied*, 454 U.S. 1098 (1981)). After weighing these factors, the Ninth Circuit affirmed an order requiring the disclosure of information after the Chinese Secrecy Bureau ordered a party “not to disclose or provide the information and documents requested by the United States District Court for the District of Oregon,” and warned that the party “shall bear any or all legal consequences should you not comply with this order.” *Id.* at 1476, 1478-79.

In *Autodesk*, the court held that:

ZWSOft also does not show that there is a genuine risk that production of its source code and related documents under the current protective order could subject ZWSOft to **liability** under Chinese state secret and privacy laws. ZWSOft is correct that China has imposed “severe” penalties upon people who have violated its state secrecy or privacy laws. But once again, **ZWSOft’s generalized, unsubstantiated claims about Chinese law do not establish that there is a “present danger that application of the PRC blocking statutes” could subject ZWSOft to liability if it produces its source code and related documents in the United States.**

2015 WL 1928184, at *8 (footnotes removed); *see also Masimo*, 2014 WL 12589321, at *3 (noting that the withholding party “has presented no evidence regarding the extent to which the Chinese government enforces its secrecy laws, or the likelihood that any criminal as opposed to only civil

or administrative penalties will be issued, making that factor similarly less persuasive in its favor”). ZHP has made no showing here of any “present danger” of any consequences to ZHP if production were to occur.

As explained above, none of these documents meets the definition of a Chinese state secret. Moreover, the extremely limited extent to which any of the documents may bear on China’s security or national interests, entirely from a non-substantive administrative perspective, is greatly outweighed by Plaintiffs’ right to obtain the discovery ordered in this litigation. Just as in *Autodesk*, this Court should hold that **“unsubstantiated claims about Chinese law do not establish that there is a ‘present danger that application of the PRC blocking statutes’ could subject [ZHP] to liability if it produces”** the above documents and therefore order their immediate production. There are no particularized or specific concerns demonstrated by ZHP. To the extent it decides any information may justify the protection of Chinese state secrecy laws, the Court should order the production of the document with only that information redacted, as ZHP’s Chinese law attorney has already agreed is **“one way to do it.”** 3/26/2021 Tr. 128:1-15.

CONCLUSION

For the foregoing reasons, ZHP has not met its burden of showing that Chinese state secret law bars the production of its documents. The Court should therefore grant Plaintiffs’ motion to compel.

Dated: May 10, 2021

/s/ Ruben Honik

Ruben Honik
GOLOMB & HONIK, P.C.
1835 Market Street, Ste. 2900
Philadelphia, PA 19103
Phone (215) 985-9177
rhonik@golombhonik.com

Respectfully Submitted,

/s/ Daniel Nigh

Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL
RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater

Adam Slater

MAZIE, SLATER, KATZ & FREEMAN, LLC

103 Eisenhower Pkwy, 2nd Flr.

Roseland, NJ 07068

Phone (973) 228-9898

aslater@mazieslater.com

/s/ Conlee S. Whiteley

Conlee S. Whiteley

KANNER & WHITELEY, LLC

701 Camp Street

New Orleans, LA 70130

Phone: (504)-524-5777

c.whiteley@kanner-law.com